



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

AUG 14 1997

Mr. Melvin S. Drozen
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Dear Mr. Drozen:

Mary Snyder, Director, Division of Programs and Enforcement Policy, Office of Seafood asked me to respond to your letter of July 17, 1997 concerning the use of carbon monoxide (CO) to enhance the red color of imported tuna steaks. Your letter reviews much of the information about these products, as discussed with you during separate telephone conversations with Mary and myself.

You state that FDA should "resolve the uncertainty over the legal status of this tuna quickly," and that "FDA needs to state clearly whether or not CO treatment of tuna, whether described as 'natural tasteless wood smoke' or otherwise, is permitted" under the Federal Food, Drug, and Cosmetic Act (the act), and if not, under which section of the act would it be considered to be adulterated.

As explained during our telephone conversations, we are not uncertain about the regulatory status of tuna that contains added CO. Carbon monoxide is neither generally recognized as safe (GRAS) as a food ingredient, nor has it been shown to be safe for use either as a food or color additive, as required by sections 409(a) and 706(a) of the act, respectively. Consequently, the Office of Seafood views the described use of CO in tuna or other food as a clear violation of the act, causing any food to which it is added to be adulterated.

Moreover, the use of CO obviously enhances the natural red color of tuna flesh, potentially causing consumers to be mislead about the true nature or value of the tuna.¹

¹ For example, see: *Concentration of Carbon Monoxide in Commercial Fish Flesh and in Fish Flesh Exposed to Carbon Monoxide Gas for Color Fixing*, Hajimu Ishiwata et. al., Journal

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Therefore, without regard to other violations under sections 402(a)(2)(C) or 402(c) of the act, the use of CO results in economic adulteration under section 402(b)(4) of the act because it makes the tuna "appear better or of greater value than it is." The fact that the addition of CO to food may result from treatment with some form of smoke or other ingredient, labeled or unlabeled, is a separate matter, it does not alter a charge of economic adulteration under section 402(b)(4). Thus, with regard to your question about labeling, we are not aware of a way to "properly" label an adulterated product so that it can be sold in the U.S.

Even approved color additives can not be used if such use is deceptive. For example, 21 CFR section 71.22 (Deception as a basis for refusing to issue regulations; deceptive use of a color additive for which a regulation has issued) underscores that there are any number of unstated limitations on uses of approved color additives:

....The issuance of a regulation for a color additive authorizing its use generally in or on a food, drug, or cosmetic shall not be construed as authorization to use the color additive in a manner that may promote deception or conceal damage or inferiority. The use of a color additive to promote deception or conceal damage or inferiority shall be considered as the use of a color additive for which no regulation has issued pursuant to section 721(b) of the act, even though the regulation is effective for other uses.

You go on to state that, in the interest of fairness, FDA "should ensure that the seafood industry is informed of its position and should take appropriate enforcement action." It is our understanding that the practice at issue is relatively new in seafood. Although we have not yet taken compliance action against tuna treated with CO, we have stated the above position to some FDA and National Marine Fisheries Service field personnel, and to others that have inquired, including persons interested in undertaking the practice in the U.S., and a trade association representing the seafood industry. Copies of this letter will also be sent to the National Fisheries Institute and the US Tuna Foundation.

Nonetheless, the agency's position on any practice that violates the act should be clear, we can not in each instance affirm it with a "clear public pronouncement," as you suggest.

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The abuse at issue is not inadvertent or subtle. It has always been incumbent upon those processing and importing foods to ensure that food is safe and in compliance with the provisions of the act, this is particularly true in the dawning era of HACCP.

Please contact me if you have additional questions.

Sincerely yours,



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